

WE CLAIM:

- 1 1. A water-soluble tablet comprising a pharmaceutically acceptable salt of metformin,
2 one or more water-soluble sugar alcohols, and one or more other water-soluble
3 excipients, wherein the tablet dissolves in less than about three minutes in about 30
4 ml of water to give a clear solution.
- 1 2. The water-soluble tablet according to claim 1, wherein the tablet dissolves in water
2 in less than about two minutes to give a clear solution.
- 1 3. The water-soluble tablet according to claim 1, wherein the tablet dissolves in water
2 in less than about one minute to give a clear solution.
- 1 4. The water-soluble tablet according to claim 1, wherein the tablet is dissolved in
2 about 20 ml of water.
- 1 5. The water-soluble tablet according to claim 1, wherein the tablet is dissolved in
2 about 15 ml of water.
- 1 6. The water-soluble tablet according to claim 1, wherein the pharmaceutically
2 acceptable salt of metformin comprises one or more of phosphate, sulfate,
3 hydrochloride, salicylate, maleate, benzoate, ethanedisulfonate, fumarate,
4 glycolate, salts of dibasic acids, fumarate, and succinate.
- 1 7. The water-soluble tablet according to claim 6, wherein the pharmaceutically
2 acceptable salt of metformin comprises hydrochloride.
- 1 8. The water-soluble tablet according to claim 1, wherein the pharmaceutically
2 acceptable salt of metformin comprises up to about 95% weight by weight of the
3 tablet.
- 1 9. The water-soluble tablet according to claim 1, wherein the one or more water-
2 soluble sugar alcohols comprise one or more of sorbitol, mannitol, spray-dried
3 mannitol, xylitol, erythritol, isomalt, hydrogenated starch hydrolysates, and
4 combinations thereof.

- 1 10. The water-soluble tablet according to claim 9, wherein the water-soluble sugar
2 alcohol comprises xylitol.
- 1 11. The water-soluble tablet according to claim 9, wherein the water-soluble sugar
2 alcohol comprises mannitol.
- 1 12. The water-soluble tablet according to claim 9, wherein the water-soluble sugar
2 alcohol comprises a mixture of xylitol and mannitol.
- 1 13. The water-soluble tablet according to claim 1, wherein the other water-soluble
2 excipients comprise one or more of binders, lubricants, sweeteners, and flavoring
3 agents.
- 1 14. The water-soluble tablet according to claim 13, wherein the binder comprises one
2 or more of soluble starch, polyvinylpyrrolidone, cellulose ethers, gums and
3 carboxyvinyl polymer(s).
- 1 15. The water-soluble tablet according to claim 14, wherein the binder comprises
2 polyvinylpyrrolidone.
- 1 16. The water-soluble tablet according to claim 13, wherein the lubricant comprises
2 one or more of polyethylene glycol, sodium propionate, sucrose, sodium chloride,
3 silicon oil, simethicone, polyvinylpyrrolidone, DL-leucine, sodium benzoate, boric
4 acid, sodium lauryl sulphate, and magnesium lauryl sulphate.
- 1 17. The water-soluble tablet according to claim 16, wherein the lubricant comprises
2 polyethylene glycol.
- 1 18. The water-soluble tablet according to claim 17, wherein the polyethylene glycol is
2 pulverized/micronised.
- 1 19. The water-soluble tablet according to claim 18, wherein the polyethylene glycol
2 has a particle size of from about 90% less than 250 μ .
- 1 20. The water-soluble tablet according to claim 17, wherein the polyethylene glycol
2 has a molecular weight of from about 3500 to about 20,000.

- 1 21. The water-soluble tablet according to claim 20, wherein the polyethylene glycol
2 has a molecular weight of from about 3500 to about 8000.
- 1 22. The water-soluble tablet according to claim 21, wherein the polyethylene glycol
2 has a molecular weight of about 6000.
- 1 23. The water-soluble tablet according to claim 21, wherein the polyethylene glycol
2 has a molecular weight of about 8000.
- 1 24. The water-soluble tablet according to claim 16, wherein the lubricant comprises
2 sodium propionate.
- 1 25. The water-soluble tablet according to claim 13, wherein the sweetener comprises
2 one or more of aspartame, saccharine sodium, glycine, lactose, dextrose, fructose,
3 maltose, sorbitol and sucrose.
- 1 26. The water-soluble tablet according to claim 25, wherein the sweetener comprises
2 aspartame.
- 1 27. The water-soluble tablet according to claim 1, wherein the one or more water-
2 soluble sugar alcohols comprise xylitol and spray-dried mannitol, the lubricant
3 comprises micronised polyethylene glycol, and the tablet dissolves in about 15ml
4 of water in less than about one minute to give a clear solution.
- 1 28. The water-soluble tablet according to claim 1, wherein the tablet further comprises
2 one or more additional antidiabetic agents selected from sulfonyl urea, glucosidase
3 inhibitor and thiazolidinedione.
- 1 29. A process for the preparation of a water-soluble tablet, the process comprising:
2 (a) mixing together a pharmaceutically acceptable salt of metformin, one or
3 more water-soluble sugar alcohols, and one or more other water-soluble
4 excipients to form a mixture, and
5 (b) compressing the mixture to form a tablet,
6 wherein the tablet dissolves in less than about three minutes in about 30 ml of
7 water to give a clear solution.

- 1 30. The process according to claim 29, wherein the tablet dissolves in water in less
2 than about two minutes to give a clear solution.
- 1 31. The process according to claim 29, wherein the tablet dissolves in water in less
2 than about one minute to give a clear solution.
- 1 32. The process according to claim 29, wherein the tablet is dissolved in about 20 ml
2 of water.
- 1 33. The process according to claim 29, wherein the tablet is dissolved in about 15 ml
2 of water.
- 1 34. The process according to claim 29, wherein the mixture is formulated into a tablet
2 by direct compression.
- 1 35. The process according to claim 29, wherein the mixture is granulated prior to
2 compression.
- 1 36. The process according to claim 35, wherein the mixture is wet granulated.
- 1 37. The process according to claim 35, wherein the mixture is dry granulated.
- 1 38. The process according to claim 29, wherein the pharmaceutically acceptable salt of
2 metformin comprises one or more of phosphate, sulfate, hydrochloride, salicylate,
3 maleate, benzoate, ethanedisulfonate, fumarate, glycolate, salts of dibasic acids,
4 fumarate, and succinate.
- 1 39. The process according to claim 29, wherein the pharmaceutically acceptable salt of
2 metformin comprises up to about 95% weight by weight of the tablet.
- 1 40. The process according to claim 28, wherein the one or more water-soluble sugar
2 alcohols comprise one or more of sorbitol, mannitol, spray-dried mannitol, xylitol,
3 erythritol, isomalt, hydrogenated starch hydrolysates, and combinations thereof.
- 1 41. The process according to claim 29, wherein the other water-soluble excipients
2 comprise one or more of binders, lubricants, sweeteners, and flavoring agents.

- 1 42. The process according to claim 41, wherein the binder comprises one or more of
2 soluble starch, polyvinylpyrrolidone, cellulose ethers, gums and carboxyvinyl
3 polymer(s).
- 1 43. The process according to claim 41, wherein the lubricant comprises one or more of
2 polyethylene glycol, sodium propionate, sucrose, sodium chloride, silicon oil,
3 simethicone, polyvinylpyrrolidone, DL-leucine, sodium benzoate, boric acid,
4 sodium lauryl sulphate, and magnesium lauryl sulphate.
- 1 44. The process according to claim 42, wherein the polyethylene glycol is
2 pulverized/micronised.
- 1 45. The process according to claim 44, wherein the polyethylene glycol has a
2 molecular weight of from about 3,500 to about 20,000.
- 1 46. The process according to claim 44, wherein the sweetener comprises one or more
2 of aspartame, saccharine sodium, glycine, lactose, dextrose, fructose, maltose,
3 sorbitol and sucrose.
- 1 47. The process according to claim 28, wherein the one or more water-soluble sugar
2 alcohols comprise xylitol and spray-dried mannitol, the lubricant comprises
3 micronised polyethylene glycol, and the tablet dissolves in about 15 ml of water
4 within about one minute to give a clear solution.
- 1 48. The process of claim 29, wherein the mixing further comprises mixing one or more
2 additional antidiabetic agents selected from sulfonyl urea, glucosidase inhibitor
3 and thiazolidinedione.
- 1 49. A method of treating diabetes mellitus comprising administering to a patient in
2 need thereof a water soluble tablet comprising a pharmaceutically acceptable salt
3 of metformin, one or more water-soluble sugar alcohols, and one or more other
4 water-soluble excipients, wherein the tablet dissolves in less than about three
5 minutes in about 30 ml of water to give a clear solution.
- 1 50. The method of claim 49, wherein the tablet further comprises one or more
2 additional antidiabetic agents selected from sulfonyl urea, glucosidase inhibitor
3 and thiazolidinedione.